

**REMARKS**

Claims 1, 4-7, 9-23, 25-27, 32-43, 45-55, 61-70 and 72-86 were pending when the present Office Action was mailed (May 4, 2007). In this response, claim 77 has been cancelled, without prejudice to pursuing this claim in unamended (or other) form in a continuation or other application, and without disclaiming subject matter withdrawn as a result of cancelling claim 77. Accordingly, claims 1, 4-7, 9-23, 25-27, 32-43, 45-55, 61-70, 72-76 and 78-86 are currently pending.

In the May 4, 2007 Final Office Action, claims 74 and 82 were allowed and the remaining claims were rejected or objected to. More specifically, the status of the application in light of the Final Office Action is as follows:

(A) The Abstract is objected to;

(B) Claim 77 is rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,944,497 to Stypulkowski ("Stypulkowski") in view of US 2002/0091419 to Firlik ("Firlik '419") and US 2002/0087201 to Firlik et al. ("Firlik '201");

(C) Claims 19-20, 22-23, 25-27, 32, 35-39, 78-79, and 86 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,938,688 to Schiff ("Schiff") in view of Firlik '419 and Firlik '201;

(D) Claims 1, 4-7, 9-12, 14-18, 21, 40-43, 45-47, 49-55, 61-70, 72-73, 75-76, 80-81, and 83-85 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Schiff in view of Firlik '419 and Firlik '201 and further in view of US 2004/0082847 to McDermott ("McDermott") and an article by Jeffrey Binder, titled "Functional Magnetic Resonance Imaging: Language Mapping," (Neurosurgery Clinics of North America) 8.3:383-392 (1997) ("Binder");

(E) Claims 13 and 48 are objected to as being dependent upon a rejected claim, but are indicated to be allowable if rewritten to be in independent form; and

(F) Claims 74 and 82 are allowed.

As a preliminary matter, and in response to the Examiner's request regarding the IDS filed on April 16, 2007, applicant has received many of the submitted references in connection with the prosecution of patent applications in the same general field as the present application, but has not conducted a detailed review of the submitted references as they apply specifically to the currently pending claims. However, applicant notes that the following references were identified in a search report conducted for a PCT application corresponding to the present application, and submitted to the U.S. Patent Office in an IDS dated October 18, 2004: US 2002/0091419A1, US Patent No. 4,844,075, and US Patent No. 4,431,000.

A. Response to the Objection to the Specification

The Abstract was objected to because the first sentence of the Abstract included the phrase "are disclosed." The Abstract has been amended to eliminate this phrase and accordingly, the objection to the Abstract should be withdrawn.

B. Response to the Rejection of Claim 77

Claim 77 has been cancelled in an effort to expedite prosecution of the present application, and without prejudice to pursuing this claim in unamended or other forms in a continuation or other application. Accordingly, the outstanding rejection of claim 77 is now moot.

C. Response to the Section 103 Rejections on the Basis of Schiff, Firlik '419 and Firlik '201

Claims 19, 20, 22, 23, 25-27, 32, 35-39, 78, 79 and 86 were rejected under 35 U.S.C. § 103 as being unpatentable over Schiff in view of Firlik '419 and Firlik '201. Claim 19 is directed to a method for treating a language disorder of a patient, and includes selecting a stimulation site of a patient's brain, with the stimulation site being located within the patient's skull, proximate to the dura mater and outside a cortical surface of the patient's brain. The method further includes positioning at least one electrode at the stimulation site, coupling the at least one electrode to a source of electrical potential, and

at least reducing a language disorder of the patient by applying electrical stimulation directly to the stimulation site via the at least one electrode while not actively engaging the patient in a language-based task.

Schiff discloses a method for treating a conscious patient having impaired cognitive functions by applying electrical stimulation to at least a portion of the patient's intralaminar nuclei (Schiff at Abstract). Schiff discloses that "the intralaminar nuclei (including the midline nuclei) are believed to be in a preferred position to modulate the large thalamo-cortical-basal ganglia loops, especially to synchronize their function" (Schiff at column 8, lines 5-9). Schiff further discloses that "[p]referably, the electrical stimulation is applied only to the patient's intralaminar nuclei or a portion thereof without stimulating other regions of the patient's brain" (Schiff at column 11, lines 32-34).

Firlik '419 and Firlik '201 both disclose methods for treating a patient via stimulation of tissue associated with neuroplasticity (e.g., Firlik '419 at Abstract). In particular embodiments, the stimulation is applied to the cortex (e.g., Firlik '419 at Figure 26).

The combination of Schiff with Firlik '419 and Firlik '201 fails to establish a *prima facie* basis for rejecting claim 19 for at least the reason that Schiff expressly teaches away from elements of this claim. For example, Schiff expressly states that the intralaminar nuclei, as opposed to any other region of the brain, are the preferred targets for electrical stimulation, stating that "[p]referably, the electrical stimulation is applied only to the patient's intralaminar nuclei or a portion thereof, without stimulating other regions of the patient's brain" (Schiff at column 11, lines 32-34, emphasis added). Schiff repeatedly underscores the importance of stimulating the intralaminar nuclei as opposed to a stimulation site "proximate to the dura mater and outside cortical surface of the patient's brain," as is expressly included in claim 19. For example, Schiff states:

"the electrode can be contacted with the patient's intralaminar nuclei by the methods conventionally employed for embedding or emplacing electrodes for deep brain electrical stimulation in other thalamic nuclei"

(Schiff at column 5, lines 53-56, emphasis added);

"the method of the present invention can further comprise selecting one or more subdivisions of the patient's intralaminar nuclei for stimulation"

(column 11, lines 39-41, emphasis added);

"[t]hus, by knowing the specific cognitive function or functions impaired in a particular patient, the preferred subdivision of the particular patient's intralaminar nuclei to receive electrical stimulation can be determined"

(column 12, lines 29-32, emphasis added); and

"it is believed that the intralaminar nuclei are directly implicated by their strong inputs from the vestibular nuclei"

(column 13, lines 20-22, emphasis added).

In light of the foregoing repeated and emphatic teaching that the intralaminar nuclei, and only the intralaminar nuclei, are to be stimulated to affect cognitive function, one of ordinary skill in the relevant art would not be led to select a stimulation site "proximate the dura mater, and outside a cortical surface of the patient's brain" as is included in claim 19. Accordingly, the Section 103 rejection of claim 19 should be withdrawn for at least the foregoing reasons.

Claims 20, 22, 23, 25-27, 32 and 35-39 depend from claim 19. Accordingly, the Section 103 rejections of these claims should be withdrawn for at least the foregoing reasons and for the additional features of these dependent claims.

Independent claims 78, 79 and 86 each include features analogous at least in part to those of claim 19, including selecting a stimulation site that is located "proximate the dura mater, and outside a cortical surface of the patient's brain." Accordingly, the Section 103 rejections of these claims should be withdrawn for at least the foregoing reasons and for the additional features of these claims.

D. Response to the Section 103 Rejections of the Basis of Schiff, Firlík '419, Firlík '201, McDermott and Binder

Claims 1, 4-7, 9-12, 14-18, 21, 40-43, 45-47, 49-55, 61-70, 72, 73, 75, 76, 80, 81 and 83-85 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Schiff in view of Firlík '419 and Firlík '201, and further in view of McDermott and Binder. Schiff, Firlík '419 and Firlík '201 were discussed above with reference to claim 19. McDermott is relied upon for its alleged disclosure of identifying one or more language regions in the brain of a subject. Binder is relied on for its alleged disclosure of using language-based tasks combined with fMRI for mapping.

Claim 1 is directed to a method for selecting a stimulation site in a language-disorder patient, and includes directing the patient to perform a language-based task, including directing the patient to repeat a noun, and directing information to be collected, with the information corresponding to a level of neural activity in the patient's brain while the patient performs the language-based task. Based at least in part on the information, the method includes selecting a stimulation site within the patient's skull proximate the dura mater, and outside a cortical surface of the patient's brain for receiving an electrode coupleable to an electrical current.

Claim 1 includes at least one feature analogous to the feature discussed above with reference to claim 19 (selecting a stimulation site "located within the patient's skull, proximate the dura mater, and outside a cortical surface of the patient's brain"). Accordingly, for at least the reasons discussed above, Schiff expressly teaches away from the features of claim 1. Schiff's express teaching away from at least this feature is not diminished in any way by McDermott's disclosure or Binder's disclosure. Accordingly, the applied references fail to establish a *prima facie* basis for rejecting claim 1 under Section 103 and therefore, the Section 103 rejection of claim 1 should be withdrawn.

Claims 4-7, 9-12, and 14-18 depend from claim 1. Accordingly, the Section 103 rejections of these claims should be withdrawn for at least the foregoing reasons and for the additional features of these dependent claims. Claim 21 depends from claim 19, discussed above, and accordingly, the Section 103 rejection of claim 21 should be

withdrawn for at least the foregoing reasons and for the additional features of this dependent claim.

Independent claims 40, 61, 72, 73, 75, 76, 80, 81 and 83-85 all include, among other features, a stimulation site that is proximate to the dura mater and outside a cortical surface of the patient's brain. Accordingly, for at least the foregoing reasons and for the additional features of these claims, the Section 103 rejections of these claims should be withdrawn.

Dependent claims 41-43, 45-47, 49-55 and 62-70 depend from one of the foregoing independent claims. Accordingly, for at least the foregoing reasons and for the additional features of these claims, the Section 103 rejections of these claims should be withdrawn.

E. Response to the Objection to Claims 13 and 48

Claims 13 and 48 were objected to as being dependent upon a rejected independent claim but were indicated to be allowable if rewritten to be in independent form. Claim 13 depends from claim 1 and claim 48 depends from claim 40. Accordingly, these claims are allowable for the reasons discussed above, and for the additional features of these dependent claims. Therefore, the objections to claims 13 and 48 should be withdrawn.

F. Response to the Indication that Claims 74 and 82 are Allowed

Claims 74 and 82 were allowed and have not been amended in this paper.


G. Conclusion

In light of the foregoing amendments and remarks, applicant's attorney respectfully requests reconsideration and allowance of all the pending claims. If the Examiner notices any informalities or other matters that may be expediently handled by telephone, she is encouraged to contact the undersigned attorney by telephone to resolve such matters.

Applicant believes no additional fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 50-0665, under Order No. 337348055US1 from which the undersigned is authorized to draw.

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Respectfully submitted,

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